

## DEPARTMENT OF DEFENSE Office of the Secretary

### Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)

**AGENCY:** Office of the Secretary, DoD.

**ACTION:** Notice of extension of cancer treatment clinical trials demonstration project.

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**SUMMARY:** This notice is to advise interested parties of a one-year extension of a demonstration project in which the DoD provides CHAMPUS reimbursement for eligible beneficiaries who receive cancer treatment under approved National Institutes of Health, National Cancer Institute (NCI) clinical trials. Participation in these clinical trials will improve access to promising cancer therapies for CHAMPUS eligible beneficiaries when their conditions meet protocol eligibility criteria. DoD financing of these procedures will assist in meeting clinical trial goals and arrival at conclusions regarding the safety and efficacy of emerging therapies in the treatment of cancer. At this time, there is insufficient demonstration data for a full evaluation of costs associated with enrollment in clinical trials. Extending the demonstration for an additional year will allow sufficient time for patient accrual to clinical trials and collection of data which allows for comprehensive economic analysis. This demonstration also affects TRICARE, the managed health care program that includes CHAMPUS. This demonstration project, which is under the authority of 10 U.S.C., section 1092, will expire December 31, 1999.

**EFFECTIVE DATE:** January 1, 1999.

**FOR FURTHER INFORMATION CONTACT:**

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**SUPPLEMENTARY INFORMATION:**

**A. Background**

On January 24, 1996, the Department provided notice in the Federal Register (61 FR 1899) of an expansion of an existing demonstration for breast cancer treatment clinical trials to include all cancer treatment clinical trials under approved National Cancer Institute (NCI) clinical trials. The demonstration purpose is to improve beneficiary access to promising new therapies, assist in meeting the National Cancer Institute's clinical trial goals, and arrival at conclusions regarding the safety and efficacy of emerging therapies in the treatment of cancer. The January 24, 1996, notice anticipated the possibility of extending the demonstration.

The NCI trials program is the principal means by which the oncology community has developed clinical evidence for the efficacy of various treatment approaches in cancer therapy. Participating institutions include NCI's network of comprehensive and clinical cancer centers, university and community hospitals and practices, and military treatment facilities. Despite this extensive network which includes the nation's premier medical centers, cure rates for most types of cancer remain disappointing, highlighting the significant effort still required for improvement. The principal means by which advances in therapy will be realized is through application of research to victims of cancer. In support of NCI's efforts to further the science of cancer treatment, the Department expanded its breast cancer demonstration to include all NCI-sponsored phase II and phase III clinical trials. This expanded demonstration will enhance current NCI efforts to determine safety and efficacy of promising cancer therapies by expanding the patient population available for entry into clinical trials and stabilizing the referral base for these clinical activities. While this demonstration provides an exception to current CHAMPUS benefit limitations, the Department hypothesizes that this increased access to innovative cancer therapies will occur at a cost comparable to that which the Department has experienced in paying for conventional therapies under the standard CHAMPUS program. Results of this demonstration will provide a framework for determining the scope of DoD's continued participation in the NCI's research efforts.

Dated: November 9, 1998.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

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